DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our Reference: OB-NDA 19-841/003

FEB 19 2002

Mallinckrodt, Incorporated
Attention: James W. Brodack, Ph.D.
Regulatory Affairs Manager
P.O. Box 5840
675 McDonnell Boulevard
St. Louis, MO 63134

Dear Dr. Brodack:

We acknowledge receipt of your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Indium In-111 Chloride Sterile Solution
NDA Number: 19-841
Supplement Number: 3
Date of Supplement: October 10, 2001
Date of Receipt: October 16, 2001

This prior approval supplemental application proposes the following change: to provide for use in radiolabeling Ibritumomab Tiuxetan (Zevalin) and to remove use in radiolabeling Imciromab Pentetate (Myoscint).

We have completed the review of this supplement and it is approved effective this date.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

We remind you that you must comply with the requirements of an approved NDA set forth under 21 CFR 314.80 and 314.81, including submission of annual reports.

If you have any questions, contact Mr. Michael Noska, Regulatory Project Manager, at (301) 827-5101.

Sincerely yours,

Patricia Keegan for Dr. Weiss

Karen D. Weiss, M.D.
Director
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